Complete Summary

GUIDELINE TITLE

Management of osteoporosis. A national clinical guideline.

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of osteoporosis. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 45 p. (SIGN publication; no. 71). [149 references]

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
CONTRAINDICATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Osteoporosis

Note: The guideline does not address corticosteroid induced osteoporosis.

GUIDELINE CATEGORY

Diagnosis
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Family Practice
Geriatrics
Internal Medicine
Obstetrics and Gynecology
Orthopedic Surgery
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Dietitians
Nurses
Patients
Physical Therapists
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To ensure the timely identification of those individuals at highest risk of osteoporosis, as well as those who already have the disease
- To explore the treatment options that can be used in these patients to reduce their increased risk of further fractures with the aim of achieving "secondary prevention of fracture"

TARGET POPULATION

Individuals at high risk for, or who currently have, osteoporosis, including women and men over 50 who present with fractures (that occur in the absence of major trauma, such as road traffic accidents)

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment

1. Assessment of risk factors including history of falls/fracture, age, sex, ethnicity, reproductive factors, family history, weight, smoking history, alcohol use, exercise, diet, and risk scores

Diagnosis

1. Techniques for measuring bone mineral density, including:
    - Dual-energy X-ray absorptiometry (DEXA or DXA)
    - Peripheral dual-energy X-ray absorptiometry (pDXA) (not recommended)
    - Peripheral quantitative computed tomography (pQCT) (not recommended)
    - Single photon absorptiometry (SPA)(not recommended)
    - Single-energy X-ray absorptiometry (SEXA or SXA) (not recommended)

- Radiograph absorptiometry

2. Techniques discussed but not specifically recommended:
    - Quantitative ultrasound (QUS) to assess bone quality and structure
    - Biochemical markers such as resorption markers to assess bone turnover
    - Quantitative computed tomography (QCT)

Treatment

Non-pharmacological

1. Exercise
2. Calcium + vitamin D
3. Interventions discussed but not specifically recommended:
    - Fluoridation of water
    - Use of ipriflavone
    - Elimination of caffeine

Pharmacological

1. Bisphosphonates (alendronate, etidronate, risedronate)
2. Hormone replacement therapy (considered but not recommended)
3. Raloxifene
4. Calcitonin

MAJOR OUTCOMES CONSIDERED

- Fracture rates and risk
- Fracture related morbidity

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The evidence base for this guideline was synthesised in accordance with Scottish Intercollegiate Guidelines Network (SIGN) methodology. A systematic review of the literature was carried out using an explicit search strategy devised in collaboration with members of the guideline development group. Searches were restricted to systematic reviews, meta-analyses, randomised controlled trials, and longitudinal studies. Internet searches were carried out on the websites of the Canadian Practice Guidelines Infobase, the UK Health Technology Assessment Programme, the US National Guidelines Clearinghouse, and the US Agency for Healthcare Research and Quality. Searches were also carried out on the search engines Google and OMNI, and all suitable links followed up. Database searches were carried out on Cochrane Library, Embase 1993 to 2000, and Medline 1990 to 2000. Searches were later updated to June 2001.

The main searches were supplemented by material identified by individual members of the development group. All selected papers were evaluated using standard methodological checklists before conclusions were considered as evidence.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort or studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The Scottish Intercollegiate Guidelines Network (SIGN) carries out comprehensive systematic reviews of the literature using customized search strategies applied to a number of electronic databases and the Internet. This is often an iterative

process whereby the guideline development group will carry out a search for existing guidelines and systematic reviews in the first instance and, after the results of this search have been evaluated, the questions driving the search may be redefined and focused before proceeding to identify lower levels of evidence.

Once papers have been selected as potential sources of evidence, the methodology used in each study is assessed to ensure its validity. SIGN has developed checklists to aid guideline developers to critically evaluate the methodology of different types of study design. The result of this assessment will affect the level of evidence allocated to the paper, which in turn will influence the grade of recommendation it supports.

Additional details can be found in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines" (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50]). Available from the SIGN Web site.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The process for synthesising the evidence base to form graded guideline recommendations is illustrated in the companion document titled "An Introduction to the SIGN Methodology for the Development of Evidence-based Clinical Guidelines." (Edinburgh [UK]: Scottish Intercollegiate Guidelines Network. [SIGN publication; no. 50], available from the SIGN Web site.

Evidence tables should be compiled, summarizing all the validated studies identified from the systematic literature review relating to each key question. These evidence tables form an important part of the guideline development record and ensure that the basis of the guideline development group's recommendations is transparent.

In order to address how the guideline developer was able to arrive at their recommendations given the evidence they had to base them on, SIGN has introduced the concept of considered judgement.

Under the heading of considered judgement, guideline development groups are expected to summarise their view of the total body of evidence covered by each evidence table. This summary view is expected to cover the following aspects:

- Quantity, quality, and consistency of evidence
- Generalisability of study findings
- Applicability to the target population of the guideline
- Clinical impact (i.e., the extent of the impact on the target patient population, and the resources need to treat them.)

Guideline development groups are provided with a pro forma in which to record the main points from their considered judgement. Once they have considered these issues, the groups are asked to summarise their view of the evidence and assign a level of evidence to it, before going on to derive a graded recommendation.

The assignment of a level of evidence should involve all those on a particular guideline development group or subgroup involved with reviewing the evidence in relation to each specific question. The allocation of the associated grade of recommendation should involve participation of all members of the guideline development group. Where the guideline development group is unable to agree on a unanimous recommendation, the difference of opinion should be formally recorded and the reason for dissent noted.

The recommendation grading system is intended to place greater weight on the quality of the evidence supporting each recommendation, and to emphasise that the body of evidence should be considered as a whole, and not rely on a single study to support each recommendation. It is also intended to allow more weight to be given to recommendations supported by good quality observational studies where randomised controlled trials (RCTs) are not available for practical or ethical reasons. Through the considered judgement process guideline developers are also able to downgrade a recommendation where they think the evidence is not generalisable, not directly applicable to the target population, or for other reasons is perceived as being weaker than a simple evaluation of the methodology would suggest.

On occasion, there is an important practical point that the guideline developer may wish to emphasise but for which there is not, nor is their likely to be, any research evidence. This will typically be where some aspect of treatment is regarded as such sound clinical practice that nobody is likely to question it. These are marked in the guideline as "good practice points." It must be emphasized that these are not an alternative to evidence-based recommendations, and should only be used where there is no alternative means of highlighting the issue.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The grade of recommendation relates to the strength of the evidence on which the recommendation is based. It does not reflect the clinical importance of the recommendation.

A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

COST ANALYSIS

Cost Effectiveness of Diagnostic Approaches

Only three relevant economic papers on the use of dual-energy X-ray absorptiometry (DXA) scanning were identified. These all involved modelling, rather than incorporation of economic evaluation into clinical trials.

There is some evidence that for relatively expensive medication, such as bisphosphonates, treatment programmes with prior bone density screening are likely to be more cost-effective than those without and, in some circumstances, become cost saving.

One recent paper concluded that diagnosis and treatment of women at risk of osteoporosis would be made more cost effective by targeting treatment to those with the lowest bone measurement results. Inclusion of another assessment, such as a risk profile, may improve the cost effectiveness of diagnosis.

Cost Effectiveness of Treatment

A recent Health Technology Assessment (HTA) examined the cost utility and cost effectiveness of different treatments for established osteoporosis. This study compared treatments using the cost per quality-adjusted life-year (QALY). It used a threshold of £30,000 or less per quality-adjusted life-year to represent cost effectiveness. Using an economic model developed by the authors, at age 50 years only hormone replacement therapy (HRT) and calcium plus vitamin D were likely to be considered cost-effective (assuming that the agent would decrease the risk of non-vertebral fractures at this age). In older age groups a wider range of treatments, including hormone replacement therapy, calcium with or without vitamin D and bisphosphonates were considered cost effective.

This Health Technology Assessment demonstrates that age is an important determinant of cost effectiveness since the risk of fractures increases with age. High costs of intervention are associated with poorer cost effectiveness since, in general, the variation in cost is greater than any proven variation in efficacy.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A national open meeting is the main consultative phase of Scottish Intercollegiate Guidelines Network (SIGN) guideline development, at which the guideline development group presents its draft recommendations for the first time. The national open meeting for this guideline was held in February 2002 and was attended by 328 representatives of all the key specialties relevant to the guideline. The draft guideline was also available on the SIGN website for a limited period at this stage to allow those unable to attend the meeting to contribute to the development of the guideline. The comments received from the national open meeting were considered when the guideline was redrafted for peer review.

The guideline was also reviewed in draft form by independent expert referees, who were asked to comment primarily on the comprehensiveness and accuracy of interpretation of the evidence base supporting the recommendations in the guideline.

As a final quality control check, the guideline is reviewed by an Editorial Group comprising the relevant specialty representatives on SIGN Council to ensure that the peer reviewers' comments have been addressed adequately and that any risk of bias in the guideline development process as a whole has been minimised.

Each member of the guideline development group then approved the final guideline for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the Scottish Intercollegiate Guidelines Network (SIGN) and National Guideline Clearinghouse (NGC): In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

The strength of recommendation grading (A-D) and level of evidence (1++, 1+, 1-, 2++, 2+, 2-, 3, 4) are defined at the end of the "Major Recommendations" field.

Risk Factors for Osteoporosis

B - Patients who have suffered one or more fragility fractures should be priority targets for investigation and treatment of osteoporosis.

C - Use of family history in assessing risk of osteoporosis should include maternal, paternal, and sister history.

C - Family history should include not only a given diagnosis of osteoporosis but also kyphosis and low trauma fracture after age 50.

B - Smokers should be considered at greater risk of osteoporosis than non-smokers, and advised to stop, for this and other reasons.

Measurement, Diagnosis and Monitoring

B - Conventional radiographs should not be used for the diagnosis or exclusion of osteoporosis.

B - When plain films are interpreted as "severe osteopaenia" it is appropriate to suggest referral for dual-energy X-ray absorptiometry (DXA).

A – Bone mineral density (BMD) should normally be measured by DXA scanning performed on two sites, preferably anteroposterior spine and hip.

B - Repeat measurements should only be performed if they influence treatment.

C - If DXA investigations are repeated, anteroposterior (AP) spine and total hip measurements should be used to follow response to treatment.

C - Following a DXA scan of the hip, the annual hip fracture risk (or 10 year fracture risk) should be included in the DXA report.

C - Where lateral spine scans acquired with fan-beam DXA are available, visual assessment should be used to assess prevalent vertebral fractures.

B - Evidence of existing vertebral deformity should be used to modify the hip fracture risk estimated from age, sex, and BMD.

A - Biochemical markers of bone turnover should have no role in the diagnosis of osteoporosis or in the selection of patients for BMD measurement.

Non-pharmacological Interventions

B - High intensity strength training is recommended as part of a management strategy for osteoporosis.

B - Low impact weight bearing exercise is recommended as part of a management strategy for osteoporosis.

A - Postmenopausal women should aim for a dietary intake of 1,000 mg calcium per day.

B - Ipriflavone should not be used as a sole therapy for fracture reduction in patients with osteoporosis.

Pharmacological Management

<u>For postmenopausal women with multiple vertebral fractures</u>

A - To reduce fracture risk at all sites: treatment with oral risedronate (5 mg daily or 35 mg once weekly + calcium <u>+</u> vitamin D).

A - To reduce vertebral fracture risk: treatment with intermittent cyclical etidronate (400 mg daily for 14 days + 500 mg calcium daily for 76 days, repeating 3 monthly cyclical therapy).

For postmenopausal women with osteoporosis determined by axial DXA and with a history of at least one vertebral fracture

A - To reduce fracture risk at all sites: treatment with oral alendronate (10 mg daily or 70 mg once weekly + calcium ± vitamin D).

A - To reduce vertebral fracture risk: treatment with oral raloxifene (60 mg daily + calcium ± vitamin D).

B - To reduce vertebral fracture risk: treatment with intranasal calcitonin (200 IU daily + calcium ± vitamin D).

For postmenopausal women with osteoporosis determined by axial DXA, with or without previous non-vertebral fracture

A - To reduce fracture risk at all sites: treatment with either oral alendronate (10 mg daily or 70 mg once weekly + calcium ± vitamin D) or oral risedronate (5 mg daily or 35 mg once weekly + calcium ± vitamin D).

A - To reduce vertebral fracture risk: treatment with oral raloxifene (60 mg per day + calcium ± vitamin D).

For frail, elderly (aged 80+ years) women with a diagnosis of osteoporosis, with or without previous non-vertebral fractures

A - To reduce fracture risk at all sites, elderly women who have suffered multiple vertebral fractures or who have had osteoporosis confirmed by DXA scanning should be considered for treatment with either oral risedronate (5 mg daily or 35 mg once weekly+ calcium ± vitamin D) or oral alendronate (10 mg daily or 70 mg once weekly + calcium ± vitamin D).

A - To reduce hip fracture risk, frail elderly women who are housebound should receive oral calcium 1,000 to 1,200 mg daily + 800 IU vitamin D.

For men with a diagnosis of osteoporosis determined by axial DXA with or without previous osteoporotic fracture

A - To reduce fracture risk at all sites, men with low BMD and/or a history of one or more vertebral fractures or one non-vertebral osteoporotic fracture should be treated with oral alendronate (10 mg + 500mg calcium ± 400 IU vitamin D daily).

Definitions:

Grades of Recommendation

A: At least one meta-analysis, systematic review of randomised controlled trials (RCTs), or RCT rated as 1++ and directly applicable to the target population; or

A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

B: A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 1++ or 1+

C: A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or

Extrapolated evidence from studies rated as 2++

D: Evidence level 3 or 4; or

Extrapolated evidence from studies rated as 2+

Levels of Evidence

1++: High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias

1+: Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias

1-: Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias

2++: High quality systematic reviews of case control or cohort studies; high quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+: Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2-: Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3: Non-analytic studies, e.g. case reports, case series

4: Expert opinion

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the management of glucocorticoid-induced osteoporosis in men and women.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduction in the incidence of fractures
- Alleviation of fracture related morbidity
- Prevention of subsequent fractures
- Identification of risk factors to provide targeted treatment

POTENTIAL HARMS

All bisphosphonates can potentially be associated with gastrointestinal side effects. For aminobisphosphonates such as alendronate, this can on rare occasions present as oesophageal ulceration. The risk of these symptoms can be lessened by the avoidance of lying flat within 30 minutes of ingestion or by using the once weekly preparations.

CONTRAINDICATIONS

CONTRAINDICATIONS

Previous history of venous thromboembolism (VTE) contraindicates oral hormone replacement therapy (HRT) or raloxifene.

QUALIFYING STATEMENTS

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- This guideline is not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered guidelines only. Adherence to them will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results.
- The ultimate judgement regarding a particular clinical procedure or treatment plan must be made by the doctor in light of the clinical data presented by the patient and the diagnostic and treatment choices available. However, it is advised that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient´s case notes at the time the relevant decision is taken.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation of national clinical guidelines is the responsibility of each National Health System (NHS) Trust and is an essential part of clinical governance. It is acknowledged that every Trust cannot implement every guideline immediately on publication, but mechanisms should be in place to ensure that the care provided is reviewed against the guideline recommendations and the reasons for any differences assessed and, where appropriate, addressed. These discussions should involve both clinical staff and management. Local arrangements may then be made to implement the national guideline in individual hospitals, units and practices, and to monitor compliance. This may be done by a variety of means including patient-specific reminders, continuing education and training, and clinical audit.

The National Osteoporosis Society (NOS) has produced an Osteoporosis Framework setting out standards for osteoporosis services in Scotland. This framework has been endorsed by the Chief Medical Officer.

The key recommendations from the National Osteoporosis Society framework document are:

- Include prevention of osteoporotic fractures in the local Health Improvement Plan (HIP)
- Identify lead clinicians in primary and secondary care to develop a local osteoporosis programme based on this framework. Each Local Health Cooperative, Primary Care, and Acute Trust should have a lead clinician for osteoporosis.
- Each Health Board should have a consultant in Public Health to assist in coordinating this osteoporosis strategy between primary and secondary care.
- Establish a local osteoporosis advisory group to facilitate multidisciplinary implementation of this framework.
- Use a selective case-finding approach to target treatment at individuals at high risk.
- Provide access to adequate levels of diagnostic and specialist services - e.g. a Local Health Care Co-operative serving a population of 50,000 would require approximately 500 dual-energy X-ray absorptiometry (DXA) scans per year.
- Promote the use of care pathways and audit to improve standards of care.
- Monitor performance to assess health impact.

Key points for audit are identified in the original guideline document.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Scottish Intercollegiate Guidelines Network (SIGN). Management of osteoporosis. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 45 p. (SIGN publication; no. 71). [149 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Jun

GUIDELINE DEVELOPER(S)

Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

Scottish Executive Health Department

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Scottish Intercollegiate Guidelines Network (SIGN) guideline development groups are required to complete a declaration of interests, both personal and non-personal. A personal interest involves payment to the individual concerned (e.g., consultancies or other fee-paid work commissioned by or shareholdings in the pharmaceutical industry); a non-personal interest involves payment which benefits any group, unit, or department for which the individual is responsible (e.g., endowed fellowships or other pharmaceutical industry support). Details of the declarations of interest of any guideline development group member(s) are available from the SIGN executive.

GUIDELINE STATUS

This is the current release of the guideline.

Any amendments to the guideline in the interim period will be noted on Scottish Intercollegiate Guidelines Network (SIGN) Web site.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site:

- HTML format
- Portable Document Format (PDF)

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Quick reference guide: Management of osteoporosis. A national clinical guideline. Scottish Intercollegiate Guidelines Network, 2003. 2 p. Available in Portable Document Format (PDF) from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.
- SIGN 50: A guideline developer´s handbook. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network. (SIGN publication; no. 50). Available from the SIGN Web site.
- Appraising the quality of clinical guidelines. The SIGN guide to the AGREE (Appraisal of Guidelines Research & Evaluation) guideline appraisal instrument. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network, 2001. Available from the SIGN Web site.

PATIENT RESOURCES

The following is available:

- Information for discussion with patients and carers. In: Management of osteoporosis. A national clinical guideline. Edinburgh (Scotland): Scottish Intercollegiate Guidelines Network (SIGN); 2003 Jun. 45 p. (SIGN publication; no. 71).

Electronic copies: Available from the Scottish Intercollegiate Guidelines Network (SIGN) Web site.

NGC STATUS

This NGC summary was completed by ECRI on April 26, 2004. The information was verified by the guideline developer on July 15, 2004.

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